

REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks and attached Declaration.

Claim 39 is pending and rejected.

In particular, on pages 2-5 of the last Office Action, claim 39 was rejected under 35 U.S.C. § 103(a) as obvious over Andersen (US 2004/0028772) in view of Cherukuri et al. (US 4,238,510) and Reiner et al. (US 5,711,961).

Applicants respectfully traverse this rejection.

Applicants note that on page 2 of the Office Action, the Examiner has alleged that the unexpected results due to the separation of sweetener such as mannitol for the active cetirizine have not been factually demonstrated. To overcome this concern, attached herewith as Attachment A is a Declaration under 37 C.F.R. 1.132. The Declaration is by one of the inventors of this application.

The Declaration compares a bilayer tablet wherein the mannitol is separated from the cetirizine to a dry formulation wherein cetirizine and mannitol coexist.

It is the Declarant's professional opinion and belief that the reduction in degradation of products of the bilayer tablet such as the claimed invention as compared to the single formulation tablet taught in the closest prior art is surprising and unexpected to one skilled in the art. In particular, the Declarant notes that it is highly unexpected that the bilayer tablet of the claimed invention is stable for at least 24 months under ICH conditions. Such unexpectedly large reduction in degradation products of mannitol esters over a formulation that has mannitol in the same layer as cetirizine is surprising and unexpected to a person of skill in the art.

Such surprising and unexpected properties of the claimed invention are not taught or suggested by the cited art. Thus, Applicants respectfully suggest that this rejection is overcome.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Domenico FANARA et al.

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